PharmaTher Announces FDA Orphan Drug Designation Granted to Ketamine for Prevention of Ischemia-Reperfusion Injury from Organ Transplantation

PharmaTher's 4th FDA orphan drug designation for ketamine

TORONTO, Dec. 15, 2022 -- PharmaTher Holdings Ltd. (the "Company" or "PharmaTher") (OTCQB: PHRRF) (CSE: PHRM), a leader in specialty ketamine pharmaceuticals, today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation for ketamine in the prevention of ischemia-reperfusion injury from organ transplantation.

The Company currently holds four orphan drug designations granted by the FDA for ketamine, which include:

1. Ketamine to prevent ischemia-reperfusion injury from organ transplantation;
2. Ketamine to treat Status Epilepticus, a rare neurological disorder requiring emergency treatment for a seizure;
3. Ketamine to treat Amyotrophic Lateral Sclerosis, a progressive neuromuscular disease with a life expectancy of only two to six years after diagnosis with no known cure; and
4. Ketamine to treat Complex Regional Pain Syndrome, a debilitating condition characterized by severe, continuous, burning or throbbing pain in a limb.

Fabio Chianelli, CEO of PharmaTher, commented: "This is our fourth orphan drug designation granted by the FDA for ketamine. We are focused on becoming the leader in providing novel ketamine solutions and our dedication to expanding ketamine's therapeutic utility in rare disorders and life-threatening conditions including, but not limited to, Parkinson's disease, Rett syndrome, amyotrophic lateral sclerosis, complex regional pain syndrome, status epilepticus, and now ischemia-reperfusion injury from organ transplantation, puts us on the right path in making ketamine more available to rare disorders potentially improving quality of life and saving lives."

According to the U.S. Organ Procurement and Transplantation Network, there were 41,355 solid organ transplantations in 2021, and thus far in 2022, there has been 39,241 solid organ transplantation with approximately 105,000 patients waiting for solid organ transplants in the United States. The four most common organs transplanted are the liver, kidney, heart, and lung. (Accessed on December 14, 2022. Available online: https://optn.transplant.hrsa.gov/data/)

IRI in organ transplantation can result in a higher incidence of acute and chronic rejection, as well as long-term morbidity and mortality. Quickly restoring blood supply of ischemic organs as soon as possible is crucial for avoiding or reducing injury from ischemia, while strategies used to attenuate the damage induced by reperfusion, include ischemic preconditioning, ischemic postconditioning, and machine perfusion. These strategies are expensive, sometimes technically challenging, and only partially effective at preventing or treating acute organ dysfunction. With a shortage of quality organs and the need for expensive medical strategies, it is clear that novel approaches to improve graft function and patient outcome are desperately needed.

Research studies have shown that ketamine lessens the injury from ischemia/reperfusion by inhibiting NF-κB thereby suppressing the production of such proinflammatory cytokines as IL-6 and TNF-α. Ketamine also shows anti-inflammatory effects by inhibiting the reactivity of leukocytes.

The Orphan Drug Act grants special status to a drug or biological product to treat a rare disease or condition upon request of a sponsor. This status is referred to as orphan designation (or sometimes "orphan status"). The FDA grants orphan status to products that treat rare diseases, providing incentives to sponsors developing drugs or biologics. The FDA defines rare diseases as those affecting fewer than 200,000 people in the United States at any given time. Orphan drug designation would qualify ketamine for certain benefits and incentives, including seven years of marketing exclusivity if regulatory approval is ultimately received for the designated indication, potential tax credits for certain clinical drug testing costs, eligibility for orphan drug grants, and the waiver of the FDA New Drug Application filing fee of approximately $2.4 million.

About PharmaTher Holdings Ltd.

PharmaTher Holdings Ltd. (OTCQB: PHRRF) (CSE: PHRM) is a specialty pharmaceutical company focused on developing and commercializing KETARX™ (ketamine) delivered by intravenous injection, microneedle patch, and wearable pump to treat mental health, neurological and pain disorders. Learn more at **PharmaTher.com**.

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